REMARKS

Claims 1, 2, 4, 6-16 and 18-25 are now pending in this application. Claims 1, 13, 14, 22 and 23 are independent claims. Claims 1, 13, 14, 22 and 23 have been amended to recite that "the cyclodextrin is at least one species selected from α-cyclodextrin and γ-cyclodextrin" from original claim 5 or 17. Accordingly, claims 5 and 17 have been cancelled without prejudice or disclaimer. Claims 1, 13, 14, 22 and 23 have also been amended to recite that the composition or obtained mixture "is used for oral administration" from original claim 3. Accordingly, claim 3 has been cancelled without prejudice or disclaimer. Claims 2 and 15 have been amended to recite that the composition "further contains an oxidized coenzyme Q for purposes of clarification and not to limit their scope. Also claims 2 and 15 have been amended to recite "the oxidized" in place of "an oxidized" for purposes of clarification and not to limit their scope. The amendments to claims 2 and 15 find support at page 7, lines 31-32 of the specification. Claim 9 has been amended to depend from claim 8 and to recite "the antioxidant" in place of "an antioxidant" for purposes of clarification and not to limit its scope. Claim 10 has been amended to recite "further contains" in place of "contains" for purposes of clarification and not to limit its scope. Claim 21 has been amended to recite "which further contains an antioxidant" and "the antioxidant" in place of "an antioxidant" for purposes of clarification and not to limit its scope. Claim 22 has been amended to recite "in the formula, n is an integer of 1 to 12" for purposes of clarification and not to limit its scope. Basis for this amendment can be found in original claims 1, 13, 14 and 21 and pages 5 and 7 in the specification. Newly presented claim 24 finds support at page 6, lines 11-13 in the specification. Newly presented claim 25 finds support at page 8, line 33 to page 9, line 4 and page 10, lines 11-13 and 23-25 of the specification. The amendments to the claims and newly presented claims do not introduce any new matter.

The rejections of Claims 2, 9, 15 and 21 under 35 USC §112, second paragraph, as being indefinite have been overcome by the above amendments to these claims.

The rejection of Claims 1, 4-10, 12-14 and 16-23 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0003122 to Gers-Barlag et al. (hereinafter

also referred to as "Gers-Barlag") in view of European Patent No. 1 440 962 to Fujii et al[1]. (hereinafter also referred to as "Fujii '962"), International Publication No. WO 03/033445 to Fujii et al.[2] (hereinafter also referred to as "Fujii '445"), U.S. Patent No. 5,486,508 to Uda et al. (hereinafter also referred as "Uda") and "Acta Poloniae Pharmaceutica" to Lutka et al. (hereinafter also referred to as "Lutka") has been rendered moot by the amendments to independent claims 1, 13, 14, 22 and 23 to include recitations from claim 3. Claim 3 was not rejected over this ground.

The rejection of Claims 1-4, 6, 7, 10-16, 18-20, 22 and 23 under 35 U.S.C. §103(a) as being unpatentable over International Publication No. WO 02/092067 to Fujii[3] (hereinafter also referred to as "Fujii '067") has been rendered moot by the amendments to independent claims 1, 13, 14, 22 and 23 to include recitations from claim 5 or 17. Claims 5 and 17 were not rejected over this ground.

Furthermore the cited references do not render obvious the present invention as now recited in the claims as amended.

The present invention, as now recited in the claims as amended, relates to a composition containing a cyclodextrin, a polar solvent and a reduced coenzyme Q represented by the general formula (1), wherein the reduced coenzyme Q is solubilized in the composition, and the cyclodextrin is at least one species selected from α-cyclodextrin and γ-cyclodextrin, and the composition is used for oral administration. The present invention also relates to a method for producing the composition.

The present invention can provide reduced coenzyme Q in the form of compositions soluble in water and, at the same time, excellent in storage stability, by the above combination of constituents.

On the other hand, Gers-Barlag relates to Pickering emulsions, which are finely dispersed systems of the water-in-oil or oil-in-water type, comprising an oil phase, a water phase, microfine particles, cyclodextrin and emulsifiers. As appreciated by the Examiner, Gers-Barlag

[1] Fujii '962 and the present application are commonly owned by Kaneka Corporation and name co-inventors that are common to both.
[2] Fujii '445 and the present application are commonly owned by Kaneka Corporation and name co-inventors that are common to both.
[3] Fujii '067 and the present application are commonly owned by Kaneka Corporation and name co-inventors that are common to both.

does not disclose emulsions comprising cyclodextrin, ubiquinol and water. Gers-Barlag only describes that Pickering emulsions are stabilized by the microfine particles.

Fujii[4] relates to an aqueous solution containing a reduced coenzyme Q and an antioxidant and/or a chelating agent. Fujii solubilizes the reduced coenzyme Q by using a liposome or a surfactant. However, Fujii does not at all disclose the cyclodextrin.

Uda relates to a powder composition which comprises a complex of a fumigillol derivative and a cyclodextrin prepared by: preparing a drug solution by dissolving the fumigillol derivative in a water soluble organic solvent, preparing a cyclodextrin solution, mixing the cyclodextrin solution into the drug solution, and lyophilizing or drying the mixed solution under reduced pressure to form a powder. Uda does not disclose the reduced coenzyme Q. Namely, Uda only discloses the fumigillol derivative as a slightly water-soluble drug, and does not at all disclose the reduced coenzyme Q as the drug. Moreover, Uda describes that the fumigillol derivative can be stabilized, but it is not clear what kind of stability is improved in Uda. One of the objects of the present invention is to stably store the reduced coenzyme Q, which is easily oxidized in the air, namely to improve the stability of the reduced coenzyme Q against oxidation. However, Uda does not at all describe this objective.

Lutka relates to the influence of cyclodextrins on coenzyme Q_{10} stability. Lutka describes that γ-cyclodextrin and methyl-β- cyclodextrin catalyzed the photolysis of coenzyme Q_{10}. Thus, Lutka does not describe reduced coenzyme Q, since coenzyme Q_{10} generally means oxidized coenzyme Q_{10} (not reduced coenzyme Q_{10}). Furthermore, Lutka does not describe the polar solvent.

As mentioned above, Gers-Barlag relates to emulsifying stabilization; in Uda it is not clear what kind of stability is improved; Lutka relates to the photolysis of oxidized coenzyme Q_{10}. Thus, none of the references even suggest solving a problem in Fujii for stabilizing reduced coenzyme Q, which is easily oxidized, against oxidation.

[4] Fujii '962 (EP 1440962) is the European national phase application of Fujii '445 (WO 03/033445). Therefore, only "Fujii" has been described instead of "Fujii '962 and Fujii '445" for linguistic economy.

Therefore, from the combination of Gers-Barlag, Fujii, Uda and Lutka, one skilled in the art would not have had a reasonable expectation of success in producing the present invention in view of stabilizing reduced coenzyme Q against oxidation.

Accordingly, from the combination of Gers-Barlag, Fujii, Uda and Lutka, one skilled in the art would not have thought that the excellent effects, such as excellent solublility in water and excellent storage stability, can be obtained by the specific combination of constituents of the composition and method of the present invention. Consequently, the present invention is unobvious from the combination of the cited references.

In view of the above, consideration and allowance are respectfully solicited.

In the event the Examiner believes an interview might serve in any way to advance the prosecution of this application, the undersigned is available at the telephone number noted below.

The Office is authorized to charge any necessary fees due with this paper to Deposit Account No. 22-0185, under Order No. 21581-00491-US from which the undersigned is authorized to draw.

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Respectfully submitted,

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